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Nucletron

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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Pre-Market Notification "Special" Section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	Nucletron Corporation
Registration #	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Contact Person:	Robert Applebaum, C.H.P., R.S.O. Director Assurance & Regulatory Affairs
Phone:.	410-312-4100
Fax:	410-312-4197

b. Device Name:

Trade/Proprietary Name:	Prostate Stepper Template Set
Common/Usual Name:	Remote Afterloading Interstitial Prostate Brachytherapy Applicator
Classification Name:	Accessory to remote afterloader 21 CFR 892.5700, Class II.

c. Comparison to Cleared Device(s)

Manufacturer	Device	510(k) #
Nucletron BV	CET Prostate Applicator Set	K990990

d. Description

The Nucletron Prostate Stepper Template Set as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment: mHDR, mHDR-Classic, mPDR and mLDR, for Interstitial Prostate brachytherapy procedures.

The Prostate Stepper Template Set consists of a template and needles used for Interstitial Prostate brachytherapy. The template is sutured to the skin surface and is designed to guide the needles into the prostate tissue. The needle hole positioning around the template will encompass the prostate volume. Once the needles are in position the middle plate is moved to tighten and to immobilize the needles within the tissue. The template attaches to an Ultrasound probe stepper device for ease of use

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when inserting the needles. Radiographic images, planar films or transverse slices, i.e. CT, MR are obtained to determine the precise location of the applicator within the body. This information is then used for brachytherapy treatment planning purposes. When the treatment planning is completed the applicator is then attached to the Nucletron remote afterloading equipment (treatment head): mHDR, mHDR-Classic, mPDR and mLDR, by the Nucletron transfer tubes. The transfer tubes lock into the open end of the applicator and the remote afterloading equipment (treatment head) prior to treatment. When the applicator is properly attached, a check cable run is performed to ensure that the applicator is properly attached and that there is no obstructions which will interrupt treatment. After the check cable run, the radioactive source will step through the applicator to deliver that prescribed dose of radiation. When the treatment is complete, the applicator is detached from the transfer tube and remote afterloading equipment. The applicator is then removed from the patient.
The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids. The applicator does not control the treatment unit; it strictly provides a treatment path for the radioactive source. The Nucletron remote afterloading system and the clinical staff verify that the applicator is properly attached prior to treatment.

e. Intended use

Nucletron Prostate Stepper Template Set is intended for use with the Nucletron remote afterloading equipment: mHDR, mHDR-Classic, mPDR and mLDR, for Interstitial Prostate brachytherapy procedures. The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

f. Summary of technological considerations

The Nucletron Prostate Stepper Template Set is substantially equivalent to the cleared device, CET Prostate Applicator Set, K#990990. It combines the functionality, components and design of the cleared device.

December 5th. 2000

Name Paul Krechting
Date

Title: Product Manager

Nucletron B.V.

Veenendaal

Netherlands

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Robert Applebaum, C.H.P., R.S.O.
Director Assurance & Regulatory Affairs
Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Re: K003270
Prostate Stepper Template Set
Dated: December 8, 2000
Received: December 13, 2000
Regulatory class: II
21 CFR 892.5700/Procode: 90 JAQ

Dear Mr. Applebaum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Nucletron

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Statement of intended use

Device Name: Prostate Stepper Template Set

Intended use

Nucletron Prostate Stepper Template Set is intended for use with the Nucletron remote afterloading equipment: mHDR, mHDR-Classic, mPDR and mLDR, for Interstitial Prostate brachytherapy procedures. The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

Prescription use

The Nucletron Prostate Stepper Template Set is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

December 5th 2000

Name: Paul Krechting
Date

Title Product Manager
Nucletron B.V.
Veenendaal
Netherlands

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003270